**Keynote Address**

**Public Health in the Shadow of the First Amendment**

**Yale Law School**

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Thank you for inviting me to speak at this important and timely conference. As a pediatrician and state public health official, I especially appreciate the chance to talk with you today.

I'd like to start by setting expectations.

My legal training is limited to two courses in health law and an introductory class in administrative law…which I audited.

So I am not angling for an honorary degree ... as much as I might like to show it to my brother, who did graduate from here and now teaches at Vanderbilt Law School.

Instead, I will speak from my judgment and experience.

Before I get into the substance of the topic, however, and as the only public health doctor speaking at this conference, I would like to clear the air of a misconception about people who work in my field ... specifically, that we are dour and humorless killjoys.

I recently spoke to public health graduates who had just earned their degrees in one of the many diverse fields, including epidemiology, environmental health science, laboratory investigation and immunology.

I had to remind them that each had passed the core curriculum.

Public Health 101 -- *How to take all the pleasure out of eating and drinking*.

Public Health 201 -- *How to turn a conversation on any topic into a discussion of antibiotic resistant sexually transmitted disease*.

And Public.Health 301 -- *How to take all the pleasure out of eating and drinking … by talking about antibiotic resistant sexually transmitted disease*.

The truth is that public health is a field full of people who enjoy life. Our premise is that the well-being of individuals, families, and communities has fundamental moral value. When people are healthy, they are productive, creative, and caring. They spend time with their friends and families, they strengthen their neighborhoods, and they help others in need.

In short, they get to live their lives.

When I think of who works in public health, I do not picture nanny-like functionaries sitting in cubicles.

Rather, I have in mind Dr. Alfred Sommer, the ophthalmologist from my neighborhood in Baltimore who recognized that Vitamin A deficiency causes not only blindness but also early death among children in the developing world. This insight was proven through extensive clinical investigation in the field. Dr. Sommer's work has saved millions of lives.

As a public health official in this country, my job has operated at a different scale. But the premise is the same -- to use tools of science to identify ways to reduce suffering and improve health.

In Baltimore, for example, after we identified a large number of babies dying in unsafe sleeping conditions … we designed and implemented a campaign to address the problem. Working with experts in behavior change and communications at the Johns Hopkins Bloomberg School of Public Health, the city developed hard-hitting advertisements in which parents who lost babies to unsafe sleep told their stories. We showed these videos across the city, including in jury rooms, and in social services offices.

Safe sleeping increased, unsafe sleep deaths declined, and now more children in our city get to live their lives.

In this context, I would like to share my concern that recent court decisions involving the First Amendment are undermining the health and well-being of the American people.

The issues under discussion at this conference are not abstract questions of law; they are matters of life and death.

About 25 years ago, the Institute of Medicine defined public health as "*what we, as a society, do collectively to assure the conditions for people to be healthy*."

I would like to discuss several "conditions for people to be healthy" that recent court decisions have put at risk … as a result of an ideology that gives tremendous weight to commercial speech but provides little deference to professional speech and public health expertise.

A condition for people to be healthy: integrity in the doctor-patient relationship

As a pediatrician, I speak with parents about their deepest fears for their children and discuss ways to avoid all sorts of threats to their health -- from HIV to teen pregnancy. I have confidential discussions with young children and teens, on complicated matters that may include abuse, sexuality, and risky behavior.

Effective medical care requires a special kind of trust between doctor and patient.

Unfortunately, recent decisions are undermining this trust.

For example, the 8th Circuit Court of appeals has upheld a South Dakota law requiring physicians to tell patients that abortion is related to a risk of suicide, after conducting its own extensive analysis of whether the language required was factual. The court got it totally wrong, with the *New England Journal of Medicine* stating flatly that the law requires physicians to tell patients information that is "false and misleading."

The *Journal*'s editors asked, "[C]an a patient trust any interaction with his or her physician knowing that the physician's very words have been mandated by the state? Patients should not accept, and our profession should not allow, physicians to become a mouthpiece of state sponsored ideology."

The 11th Circuit Court of Appeals recently upheld a Florida law that makes physicians subject to discipline for asking about gun ownership in many circumstances -- including in circumstances recommended by professional guidelines.

In dismissing the idea that this censorship violated a physician's First Amendment rights, the Court found that First Amendment protections "approach a nadir … when professionals speak privately, in the course of his or her professional judgment, to a person receiving the professional's services." And then cited a case involving professional financial advisers.

The contrast between the Court's low regard for the speech of physicians and the high regard for commercial speech is striking.

In *Sorrell vs. IMS Health*, the Supreme Court blocked a law from Vermont to protect the doctor-patient relationship by prohibiting the sale of data to pharmaceutical companies that would identify which doctors wrote which prescriptions. The Court applied a heightened form of scrutiny, treating the sharing of prescribing data for marketing to physicians among the most protected speech in our nation.

A condition for people to be healthy: An effective regulatory framework for drugs, devices, and biologics.

This means a regulatory framework that protects the public from unsafe products and incentivizes the private sector to develop products that really help patients.

At the turn of the 20th century, companies sold “patent” remedies with hidden ingredient lists and all sorts of outlandish claims. There was little incentive for research on safety or effectiveness. Starting with the Pure Food and Drug Act of 1906, the agency that would become the FDA slowly asserted itself. One tragedy after another led to change. FDA began to require testing for safety, then effectiveness, before marketing. After legislation to require this evidence passed Congress in 1962, the Institute of Medicine found insufficient evidence for two-thirds of grandfathered products, thousands in total, which were removed from the market.

FDA’s regulatory structure gives companies a strong incentive for rigorous testing, which has led to better data, more therapeutic options, and leaps forward in patient care.

It is now widely acknowledged that the foundation of restrictions on off-label promotion is at risk. Most recently, on the basis of several lower court decisions, six companies have asked FDA to substantially loosen its restrictions on off-label promotion, citing “important constitutional concerns.”

The logic of this view appears to be that companies have First Amendment Protection under the doctrine of commercial speech to promote their products with any statements that are technically true -- such as, in a survey, four out of five doctors recommend a particular drug for a particular indication; or this one specific study found that a handful of patients improved.

Such communications can be highly misleading. Peer review of scientific papers does not come close to the scrutiny applied by FDA to data. Publication bias means that positive studies are far more likely to be published; the FDA can insist on getting all studies, whether published or not.

This trend in First Amendment law also undermines the key incentive for companies to produce compelling data for their products. Every one of us here is likely to be a patient someday, and when that day comes, the consequence of inadequate research will not be a theoretical legal concern.

<u>A condition to be healthy: effective tobacco control policy.</u>

Tobacco is the nation’s leading cause of preventable death, and it kills nearly 6 million people around the world each year. Tobacco companies are also convicted racketeers who use the tools of advertising, marketing, and product manipulation to addict young people.

The history of the 20th century illustrates the danger of inadequate tobacco regulation. Among other problems, cigarette manufacturers marketed their products using a series of dubious claims and inferences, all designed to provide reassurance on the health question.

These included that doctors preferred certain brands and that light and low tar brands were safer -- what some have justifiably called the largest fraud ever perpetrated on U.S. consumers.

Finally, nearly 50 years after the U.S. Surgeon General linked cigarettes to lung cancer, Congress passed and President Obama signed legislation that would provide for significant restrictions and oversight of the tobacco industry. I would venture to say that this is a law arguably better designed to "promote the general welfare" than virtually any other on the books.

The First Amendment challenges, ironically, not only could block key progress on tobacco, but they could create a legal right to the very kind of marketing that created the public health disaster in the first place.

In 2012, the D.C. Court of Appeals struck down FDA's effort to put graphic warning labels on cigarettes -- despite evidence of their value from leading public health authorities around the world … and despite the fact that these warning labels represent the standard for tobacco control in the world under the Framework Convention on Tobacco Control.

In reaching this decision, the Court took commercial speech to a place so ideological … that there is no legitimate role for public health to protect against cancer, heart disease, lung disease, and low birthweight from tobacco. The judges actually wrote in a footnote, "We are skeptical that the government can assert a substantial interest in discouraging consumers from purchasing a lawful product, even one that has been conclusively linked to adverse health consequences."

FDA has gone back to the drawing board in order to try to thread the needle and find a path that the courts will find acceptable. Even if successful, however, the delay will be measured not only in years but also in years lost to addiction and illness.

The First Amendment looms over other possible tobacco regulation, including plain packaging, other marketing restrictions, and even the FDA's ability to review evidence and control marketing messages that certain products may be less addictive or pose less of a health risk. The result could be a legal right to conduct the same kind of advertising that deceived the nation for decades around light and low tar cigarettes.

One challenge with all these cases is that the legal decision and public health harm can be separated by years.

In 2002, the Supreme Court decided *Thompson vs. Western States*, finding that FDA's bar on pharmacies advertising compounded medications violated the First Amendment. This decision had the effect of undermining FDA's oversight of compounding.

Despite the far greater risk of compounded medications ... particularly sterile compounded medications … particularly sterile compounded medications injected into the spinal fluid …. compared to medications that have passed through the approval process, the

agency was forbidden to keep pharmacies from advertising their products nationally. One of those that marketed aggressively was called the New England Compounding Center, which sold a contaminated product that led to dozens of deaths, and hundreds of cases of meningitis.

As the Secretary of the Department of Health and Mental Hygiene in Maryland, I was responsible for tracking down these contaminated products across our state. Marylanders suffered from meningitis and other complications. This outbreak harmed the people I am responsible for.

Many factors contributed to the outbreak, including failures of oversight. However, as in a hospital seeking to avoid a catastrophic medical error, multiple, redundant levels of protection are important to protect consumers. Had FDA's approach been allowed to stand, the scale of the suffering could only have been less.

In the case of compounding, there is little dispute that FDA has the authority to ban the practice altogether. Permitting small amounts of compounding without massive, national marketing was a reasonable way to proceed. By striking down this balance, the Supreme Court shares responsibility for the suffering and death that ensued.

"*What we, as a society, do collectively to assure the conditions for people to be healthy*."

So far, I've been talking about the "conditions for people to be healthy."

I'd like to turn to the first part of the definition. "What we, as a society, do collectively …" It is this first part that reflects the fact that public health is a choice. We, as a society, have the ability to adopt an extreme view of commercial speech and the First Amendment, tie our own hands on public health, and accept the consequences.

But in the United States of America, we have not made this choice.

Such a choice would require the explicit understanding and acknowledgment that we are trading our health for an ideological view of commercial speech.

But this tradeoff is rarely, if ever, conceded in court opinions.

For example, the *Sorrell* decision essentially ignored evidence of the impact of data-driven pharmaceutical marketing on patient care. The 8th Circuit came up with its own medical judgments on abortion and suicide.

The DC Circuit in its decision on graphic warning labels conducted its own "scientific analysis," which I put in quotation marks. Spewing sarcasm, the Court managed to reach the opposite conclusion of the world's leading medical and public health authorities.

It is much easier for a Court to assert there is no evidence of benefit from warning labels that admit a genuine tradeoff between an ideological view of commercial speech and health.

So the violation of public health is twofold. Courts are not only, through their decisions, undermining the conditions for people to be healthy. Courts are, by the way they are making these decisions, undermining collective process by which we can act together to create the conditions to live longer, happier, and more fulfilling lives.

This failure to acknowledge the consequences of their legal theories is an intellectual weakness. It is cowardly.

It also suggests a way to respond.

Journalists, public health officials, and their legal colleagues must work to connect court decisions to their human consequences. It should be embarrassing for judges to ignore the evidence and judgment of professional authorities and write screeds masquerading as scientific reviews. We should be especially critical of evasions and denials that allow the courts to avoid responsibility for their actions.

I know that in the national security context, it has been argued that the Constitution is not a suicide pact.

HaveI would argue in the public health context, the First Amendment is not a suicide pact.

As law review articles by Dean Robert C. Post and others have set out, there is plenty of room in the U.S. Constitution for the courts to support freedom of speech without undermining the health and well-being of the American people.

There is plenty of room for courts to defer to medical and public health professions on important questions of medicine and public health.

Success will require re-legitimizing public health. In my view, it is too easy now for judges to look past public health judgment and evidence. We must work hard to earn greater popular support for science-based decisionmaking and policy and counter ridiculous myths about our field.

For motivation, we need only glance at the photos in our wallets and on our phones, think of the friends and neighbors in our communities, and consider the vital need for a strong and healthy United States of America into the future.

Thank you again for inviting me to this conference, and I look forward to your questions.